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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,827	04/23/2001	Andrew J Garman	3764-78	3757

7590 12/11/2001

Nixon & Vanderhye
1100 North Glebe Road 8th Floor
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EXAMINER
COUNTS, GARY W

ART UNIT	PAPER NUMBER
1641	6

DATE MAILED: 12/11/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

NIXON & VANDERHYE PC
2001 DEC 17 PM 11: 25

DOCKETED

CLT/MATTER # 3764-78
MAIL DATE 12/11/01
DUE DATE March 11, 2002
FINAL DEADLINE June 11, 2002
DOCKETED BY MGS

Office Action Summary	Application No.	Applicant(s)	
	09/763,827	GARMAN, ANDREW J	
	Examiner	Art Unit	
	Gary W. Counts	1641	

-- Th MAILING DATE of this communication app ars on the cov r sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

1. The disclosure is objected to because of the following informalities:

The specification is lacking a section entitled Brief Description of the Drawings.

Page 2, line 16 "general" should be --generally--.

Drawings are not allowed in the specification. See 37 CFR 1.81 for drawing standards and 35 U.S.C. 113. Pages 13 and 14 require cancellation of drawings. If applicant submits drawings for the description in pages 13 and 14, an update to the specification is required under the section entitled Brief Description of the Drawings.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 10, "optionally" is vague and indefinite. It is unclear if the ligand is required. See also deficiencies found in claim 2, line 22, claim 7, line 16 and claim 8, line 26.

Claim 1, line 10 "the compound" there is insufficient antecedent basis for this limitation.

Claim 1, line 12 the last couple of words are obscured, but it is interpreted to mean ligand out. Appropriate correction is required.

Claim 2, line 24 "the compound" there is insufficient antecedent basis for this limitation.

Claim 4, line 31 "the outlet" there is insufficient antecedent basis for this limitation.

Claim 5 should depend from claim 4 instead of claim 3 because claim 4 contains the features claim 5 is referring to.

Claim 5, line 1 "the area of laminar flow" there is insufficient antecedent basis for this limitation.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than on year prior to the date of application for patent in the Unit d States.

4. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Yager et al (WO 97/47390).

Yager et al disclose a microdevice comprising (1) a sample stream inlet; (2) an extraction stream inlet; (3) an extraction channel in fluid communication with sample stream inlet and extraction stream inlet for receiving a sample stream from sample stream inlet in adjacent laminar flow with an extraction stream from extraction stream inlet; (4) and two outlets which divide the laminar flow into a by-product stream outlet and a product outlet (page 3, line 17 to page 4, line 8). This device is illustrated in figure 2, where the diffusion region, of length "L" is represented by "7" (see also page 23, lines 7-20). Yager et al also disclose the use of a detector with the device to detect the presence of desired analyte particles (page 19, lines 14-23).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yager et al (WO 97/47390) in view of Wu et al (US Patent 6,297,061).

See above for teachings of Yager et al.

Yager et al differ from the instant invention in failing to disclose introducing a liquid and introducing a mixture comprising a test compound, a receptor and a ligand.

Yager et al also fail to disclose detecting the diffusion of the test compound, or the ligand out of the diffusion region.

Yager et al disclose introducing in one inlet a mixture comprised of antigen, antibody and analyte. An extraction fluid is introduced in another inlet and the two streams join in adjacent laminar flow in joining a channel (col 7. lines 48-64, see also figure 7). This allows for the movement of different layers of fluid and particles next to each other in a channel without any mixing other than diffusion (col 1, lines 42-44) and also allows for simultaneous chemical reaction (col 1, lines 49-50). Yager et al also disclose detecting the diffusion of the test compound, or ligand out of the diffusion region. Yager et al disclose that competitive immunoassays can be incorporated into the method and that at the downstream end of the crossbar (conduit), the residual sample stream and the product stream divide into the two downstream arms of the device and that the product particles can then be detected in the product stream. The detection of the product particles can be performed by using optical, electrical, chemical, electrochemical or calorimetric analysis (col 2, lines 18-58). This allows for simultaneous chemical reaction, which facilitates the elimination of preprocessing of specimens containing particulate constituents, thus reducing the sample size and analytical time required (col 1, lines 49-53).

It would have been obvious to one of ordinary skill in the art to incorporate introducing an extraction fluid and a mixture as taught by Wu et al into the device of Yager et al because Wu et al teaches that this allows for the movement of different

layers of fluid and particles next to each other in a channel without any mixing other than diffusion and also allows for simultaneous chemical reaction.

It would also have been obvious to one of ordinary skill in the art to incorporate detection of immunoassay components as taught by Wu et al into the device of Yager et al because Wu et al shows that this allows for simultaneous chemical reaction, which facilitates the elimination of preprocessing of specimens containing particulate constituents, thus reducing the sample size and analytical time required.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Shaw et al (US Patent 5,961,832) disclose an apparatus for carrying out a diffusive transfer process between first and second immiscible fluids (col 1, lines 40-46).

Giddings et al (US Patent 4,737,268) disclose a new process and apparatus for particle fractionation (col 1, lines 5-42).

Weigl et al. (US Patent 6,171,865) disclose microsensors and methods for analyzing the presence and concentration of small particles in streams containing these small particles by diffusion principles (col 4, line 66 to col 5, line 6).

Yager et al (US Patent 5,716852) disclose a channel-cell system for detecting the presence and/or measuring the presence of analyte particles in a sample stream.

Yager et al (US Patent 5,932,100) disclose a microfabricated extraction system and method for extracting desired particles from a sample stream containing desired and undesired particles.

Yager et al (US Patent 5,971,158) disclose an extraction device for extracting desired particles from a sample stream.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gary W. Counts
Examiner
Art Unit 1641
December 3, 2001

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
12/3/01

Notice of References Cited	Application/Control No. 09/763,827	Applicant(s)/Patent Under Reexamination GARMAN, ANDREW J	
	Examiner Gary W. Counts	Art Unit 1641	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification	
	A	US-6297061	10-2001	Wu et al	436	518
	B	US-5961832	10-1999	Shaw et al	210	634
	C	US-4737268	04-1988	Giddings et al	209	12.2
	D	US-6171865	01-2001	Weigl et al	436	52
	E	US-5716852	02-1998	Yager et al	436	172
	F	US-5932100	08-1999	Yager et al	210	634
	G	US-5971158	10-1999	Yager et al	209	155
	H	US-				
	I	US-				
	J	US-				
	K	US-				
	L	US-				
	M	US-				

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification	
	N						
	O						
	P						
	Q						
	R						
	S						
	T						

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.